

CLAIM

1. A method of treatment of a health condition associated with modulation of immunity which method comprises administering a standardized herbal extract prepared from the plant *Tinospora cordifolia*.
2. A method of treatment of a health condition associated with modulation of immunity which method comprises administering a standardized herbal extract prepared from the plant *Tinospora cordifolia* in conjunction with another treatment for the health condition.
3. A method of treatment according to claim 1, in which the herbal extract is standardized on the basis of its immunomodulatory activity as measured by its potential to increase phagocytosis by polymorphonuclear leukocytes by a value of not less than 20% over a base value, and on the basis of its constituents, one of which has a mass spectrometric M⁺ value of m/z 480 mass units and is present to an extent of not less than 35% of the two identified peak areas of the liquid chromatography mass spectrometry single ion recording (LC-MS SIR) chromatogram, and the second of which has a mass spectrometric M⁺ value of m/z 341 mass units and is present to an extent of not more than 65% of the two identified peak areas of the LC-MS SIR chromatogram of the methanol soluble content of said extract.
4. A method of treatment of a health condition associated with modulation of immunity according to claim 2, in which the herbal extract is standardized on the basis of its immunomodulatory activity as measured by its potential to increase phagocytosis by polymorphonuclear leukocytes by a value of not less than 20% over a base value, and on the basis of its constituents, one of which has a mass spectrometric M⁺ value of m/z 480 mass units and is present to an extent of not less than 35% of the two identified peak areas of the liquid chromatography mass spectrometry single ion recording (LC-MS SIR) chromatogram, and the second of which has a mass spectrometric M⁺ value of m/z 341 mass units and is present to an extent of not more than 65% of the two identified

peak areas of the LC-MS SIR chromatogram of the methanol soluble content of said extract.

5. A method of treatment of a health condition associated with alteration or modulation of immunity which method comprises administering a standardized herbal extract prepared from the plant *Tinospora cordifolia* wherein the herbal extract is standardized on the basis of its immunomodulatory activity as measured by its potential to increase phagocytosis by polymorphonuclear leukocytes by a value of not less than 20% over a base value, and on the basis of its constituents, one of which has a mass spectrometric M⁺ value of m/z 480 mass units and is present to an extent of not less than 35% of the two identified peak areas of the liquid chromatography mass spectrometry single ion recording (LC-MS SIR) chromatogram, and the second of which has a mass spectrometric M⁺ value of m/z 341 mass units and is present to an extent of not more than 65% of the two identified peak areas of the LC-MS SIR chromatogram of the methanol soluble content of said extract in conjunction with another therapy for the health condition.

6. The method of treatment according to claim 2, wherein the condition is osteomyelitis.

7. The method of treatment according to claim 4, wherein the condition is osteomyelitis.

8. The method of treatment according to claim 5, wherein the condition is osteomyelitis.

9. The method of treatment according to claim 2, wherein the condition is cancer.

10. The method of treatment according to claim 4, wherein the condition is cancer.

11. The method of treatment according to claim 5, wherein the condition is cancer.

12. The method of treatment according to claim 2, wherein the

condition is breast cancer.

13. The method of treatment according to claim 4, wherein the condition is breast cancer.

14. The method of treatment according to claim 5, wherein the condition is breast cancer.

15. The method of treatment according to claim 2, wherein the condition is type 1 diabetes.

16. The method of treatment according to claim 4, wherein the condition is type 1 diabetes.

17. The method of treatment according to claim 5, wherein the condition is type 1 diabetes.

18. The method of treatment according to claim 2, wherein the condition is tuberculosis, lower respiratory tract infections, tonsillitis, otitis media, hepatitis, cancer, AIDS, diabetes mellitus, diabetic ulcers, burns or pediatric disease.

19. The method of treatment according to claim 4, wherein the condition is tuberculosis, lower respiratory tract infections, tonsillitis, otitis media, hepatitis, cancer, AIDS, diabetes mellitus, diabetic ulcers, burns or pediatric disease.

20. The method of treatment according to claim 5 wherein the condition is tuberculosis, lower respiratory tract infections, tonsillitis, otitis media, hepatitis, cancer, AIDS, diabetes mellitus, diabetic ulcers, burns or pediatric disease.

21. The method according to claim 2, wherein the condition is a respiratory tract disease.

22. The method according to claim 4, wherein the condition is a respiratory tract disease.

23. The method according to claim 5, wherein the condition is a respiratory tract disease.

24. The method according to claim 2, wherein the condition is chronic

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bronchitis.

25. The method according to claim 4, wherein the condition is chronic bronchitis.

26. The method according to claim 5, wherein the condition is chronic bronchitis.

27. The method according to any one of claims 1 to 26, wherein the daily dosage is 1-50 mg/kg of body weight.

28. The method according to any one of claims 1 to 26, wherein the daily dosage is from 25mg to 1500 mg.

29. A process for preparation of the standardized extract of *Tinospora cordifolia* which comprises treating the plant material with water at an elevated temperature, filtering and concentrating to provide an extract that meets the defined standardization limits as its immunomodulatory activity as measured by its potential to increase phagocytosis by polymorphonuclear leukocytes by a value of not less than 20% over a base value, and has one constituent which has a mass spectrometric M⁺ value of m/z 480 mass units and is present to an extent of not less than 35% of the two identified peak areas of the liquid chromatography mass spectrometry single ion recording (LC-MS SIR) chromatogram, and has a second constituent which has a mass spectrometric M⁺ value of m/z 341 mass units and is present to an extent of not more than 65% of the two identified peak areas of the LC-MS SIR chromatogram of the methanol soluble content of said extract.

30. An extract of *Tinospora cordifolia* prepared by the process comprising treating the pulverized above ground parts of the plant *Tinospora cordifolia* with water at an elevated temperature, filtering and concentrating to provide an extract that has immunomodulatory activity as measured by its potential to increase phagocytosis by polymorphonuclear leukocyte by a value of not less than 20% over a base value, and has one constituent which has a mass spectrometric M⁺ value of m/z 480 mass units and is preset to an extent of not less than 35% of the two identified peak areas of the liquid chromatography mass

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spectrometry single ion recording (LC-MS SIR) chromatogram, and has a second constituent which has a mass spectrometric M⁺ value of m/z 341 mass units and is present to an extent of not more than 65% of the two identified peak areas of the LC-MS SIR chromatogram of the methanol soluble content of said extract.

31. A composition comprising the extract of claim 30.

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